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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,198	03/01/2002	Daryl Real	5407/1J328-US1	8576
7590 02/26/2004			EXAMINER	
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			JAGOE, DONNA A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

### Office Action Summary

**Application No.**

10/087,198

**Applicant(s)**

REAL ET AL.

**Examiner**

Donna Jagoe

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

***Claims 1-6 are pending in this application.***

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Samland et al. Proc. Am. Assoc. Swine Practitioners, 1998.

The claims are drawn to a method of enhancing the reproductive performance (farrowing rate) of a sow comprising feeding a sow during gestation and optionally during lactation, breeding and/or prebreeding amounts of l-carnitine or a salt thereof and a trivalent chromium salt sufficient to enhance the reproductive performance of said sow. The sow is fed about 9 to 34,000 mg/day of l-carnitine and from 0.05 to 10 ug/day of trivalent chromium salt.

Samland et al. teach administration of chromium and l-carnitine for increased farrowing rate when fed for at least 6 weeks before breeding. It also enhanced birth

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weight, sow weight gain and subsequent farrowing, total born and born alive. Both chromium and carnitine influence insulin signaling and may affect the number of follicles maturing and ovulating at estrus. Sows fed 200 ppb chromium picolinate (CrP) throughout the growth and reproductive phases farrowed 2.32 more live pigs than control. In 847 first or second parity pigs, 200 ppb CrP fed at breeding and during gestation increased farrowing rate by 13.4% while litter size was the same for parity 1 and 2 pigs. CrP (200 ppb) fed for 157 days before farrowing numerically increased litter size in all parities except 4. Sows fed 200 ppb CrP for 35 days after mating showed an increase in farrowing rate (86% vs. 82%) in only 1 of 2 trials (see abstract). See Table 3, where farrowing rate increased 13.4%.

Samland et al. teach that the goal of swing reproductive management is to increase the rate of reproductivity. Research indicates that increasing insulin levels prior to breeding causes an increase in the frequency of luteinizing hormone (LH) from the anterior pituitary and in increase in the ovulation rate. Increase in the number of follicles ovulating would be expected to increase litter size. L-Carnitine and chromium nicotinate are two nutrients that influence insulin signaling which suggest they may affect the number of follicles maturing and ovulating at estrus. These two nutrients may be important for stimulating ovulation rate in gilts. Chromium nicotinate and L-Carnitine appear to have different mechanisms of action and potentially could synergize to promote follicular growth and ovulation rate (page 70, column 2, 2<sup>nd</sup> paragraph).

Therefore, ongoing research is evaluating the effects of additional L-Carnitine and/or

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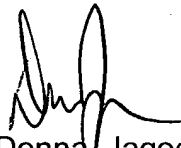
chromium nicotinate on ovulation and embryo implantation rate in gilts (age 70-71, see summary).


### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 9:00 A.M. - 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (571) 272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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Art Unit 1614

  
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